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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/668,248 | 09/24/2003 | Eckard Weber | 2009.0010005 | 4290 |

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| EXAMINER | |
|---|---|
| WINSTON, RANDALL O | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1655 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/668,248 | WEBER ET AL. | |
| | Examiner | Art Unit | |
| | RANDALL WINSTON | 1655 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *14 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *35-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1107*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**DETAILED ACTION**

Acknowledgement of the receipt and entry of the amendment filed on 05/14/2007.

The rejection made under 35 U.S.C. 103(a) set forth in the previous office action has been overcome by Applicant's amendment.

Examiner has acknowledged that claims 1-34 have been cancelled.

Examiner has acknowledged that new claims 35-45 have been added.

Claims 35-45 will be examined on the merits.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 35-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grenfell et al. (US 6416323) in view of Watt-Smith (US 4659714).

Applicants claim a dental cartridge said cartridge fits into a standard local anesthetic syringe wherein the cartridge contains a composition comprising phentolamine mesylate in various amounts and a pharmaceutical carrier.

Grenfell et al. teach a dental cartridge said cartridge fits into a standard dental local syringe wherein the cartridge contains a composition comprising substances to improve local anesthesia for dentistry or oral surgery (please note that a pharmaceutical carrier is known to be water) (see, e.g. abstract and column 9 lines 18-33). Grenfell

does not teach the claimed substance of the active ingredient of phentolamine mesylate within the cartridge that fits into a standard dental local syringe.

Watt-Smith benefically teaches that phentolamine or its salts is useful to improve local anesthesia for dentistry or oral surgery (please note that phentolamine and its salts improved local anesthesia for dentistry or oral surgery as being used as an alpha-adrenoreceptor blocking agent to reduce prolongation of anesthesia by vasoconstrictor) (see, e.g. entire patent including Table 1).

One of ordinary skill in the art of creating the claimed invention would have been motivated to substitute Grenfell's claimed active ingredient substance within its claimed dental cartridge with the active ingredient of a phentolamine or its salts as taught by Watt-Smith because the above combined two references as a whole would create the claimed invention's dental cartridge said cartridge fits into a standard dental local syringe wherein the cartridge contains a composition comprising phentolamine mesylate to improve local anesthesia for dentistry or oral surgery. Moreover, as discussed in MPEP Section 2114.06, "it is *prima facie* obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (e.g. to improve local anesthesia for dentistry or surgery), in order to form a third composition to used for the same purpose". Moreover, according to Watt-Smith's Table 1, it is clear to the Examiner that most of the reduction of the prolonged anesthetic effect takes place between 0mg to 1mg. It is also clear to Examiner that between 1mg to 3mg that the reduction of the prolonged anesthetic appears to be approximately linear and only slightly changing. Therefore, it would be obvious to one of ordinary skill in the art to

modify Watt-Smith's phentolamine amount by lowering the disclosed amount to under 1mg, e.g. to the instantly claimed amounts of about 0.0018mg and about 0.45 mg, because according to Watt-Smith Table 1, an amount under 1mg is expected to have a beneficial effect of the reduction of the prolonged anesthetic effect not significantly different than a amount over 1mg which is nearly linear. Furthermore, the adjustment of other convention working conditions (e.g. although it is well known to one of ordinary skill in the art that in order for the cartridge to be able to fit into standard dental syringe, the cartridge would have to have a volume of between 1.6 ml and 1.8 ml), is deemed a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant's arguments filed on 05/14/2007 have been carefully considered but they are not deemed persuasive. Applicant argues Watt-Smith discloses the use of phentolamine mesylate and other alpha adrenergic receptor antagonists to reduce the prolongation of anesthesia. However, Watt-Smith is silent regarding the levels of antagonist to use. In particular, Watt-Smith fails to teach or suggest the low concentrations and low doses present in the claimed cartridges, which Applicants have unexpectedly shown to be effective to reverse anesthesia.

Although Applicant argues Watt-Smith fails to teach or suggest the low concentrations and low doses present in the claimed cartridges, Examiner in this final

rejection has now provided the entire Patent of Watts-Smith (e.g. US 4659714). Therefore, Applicant argument is still not found persuasive because according to Watt-Smith's Table 1, it would be obvious to one of ordinary skill in the art to modify Watt-Smith's phentolamine amount by lowering the amount to under 1mg to the e.g. claimed amounts of about 0.0018mg and about 0.45 mg, because according to Watt-Smith Table 1, a claimed amount under 1mg has nearly the same beneficial effect of the reduction of the prolonged anesthetic effect as an amount over 1mg which has a nearly linear response to the amount of phentolamine between 1 and 3 mg.

Therefore, Grenfell et al. teach a dental cartridge said cartridge fits into a standard dental local syringe wherein the cartridge contains a composition comprising substances to improve local anesthesia for dentistry or oral surgery (please note that a pharmaceutical carrier is known to be water) (see, e.g. abstract and column 9 lines 18-33). Grenfell does not teach the claimed substance of the active ingredient of phentolamine mesylate within the cartridge that fits into a standard dental local syringe.

Watt-Smith benefically teaches that phentolamine or its salts is useful to improve local anesthesia for dentistry or oral surgery (please note that phentolamine and its salts improved local anesthesia for dentistry or oral surgery as being used as an alpha-adrenoreceptor blocking agent to reduce prolongation of anesthesia by vasoconstrictor) (see, e.g. entire patent including Table 1).

One of ordinary skill in the art of creating the claimed invention would have been motivated to substitute Grenfell's claimed active ingredient substance within its claimed dental cartridge with the active ingredient of a phentolamine or its salts as taught by

Watt-Smith because the above combined two references as a whole would create the claimed invention's dental cartridge said cartridge fits into a standard dental local syringe wherein the cartridge contains a composition comprising phentolamine mesylate to improve local anesthesia for dentistry or oral surgery. Moreover, as discussed in MPEP Section 2114.06, "it is *prima facie* obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (e.g. to improve local anesthesia for dentistry or surgery), in order to form a third composition to used for the same purpose". Moreover, according to Watt-Smith's Table 1, it is clear that most of the reduction of the prolonged anesthetic effect takes place between 0mg to 1mg. It is also clear that between 1mg to 3mg that the reduction of the prolonged anesthetic appears to be approximately linear and changing little. Therefore, it would be obvious to one of ordinary skill in the art to modify Watt-Smith's phentolamine amount by lowering the amount to under 1mg, to e.g. the claimed amounts of about 0.0018mg and about 0.45 mg, because according to Watt-Smith Table 1, a amount under 1mg has most of the beneficial effect of the reduction of the prolonged anesthetic effect. Furthermore, the adjustment of other convention working conditions (e.g. although it is well known to one of ordinary skill in the art that in order for the cartridge to be able to fit into standard dental syringe, the cartridge would have to have a volume of between 1.6 ml and 1.8 ml), is deemed a matter of judicial selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

**No claims are allowed.**

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RANDALL WINSTON whose telephone number is (571)272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jon P Weber/

Supervisory Patent Examiner, Art Unit 1657

| Application Number | Application/Control No. | Applicant(s)/Patent under Reexamination | |
|---|---|---|---|
| | 10/668,248 | WEBER ET AL. | |
| | Examiner | Art Unit | |
| | RANDALL WINSTON | 1655 | |